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Modification No. 1

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INTERAGENCY AGREEMENT BETWEEN THE CONSUMER PRODUCT SAFETY COMMISSION (CPSC) AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) (00FED05404-01)

This document sets forth the terms of agreement for services, supplies, and/or material between the U.S. Consumer Product Safety Commission (CPSC) and the Department of Health and Human Services (DHHS), Centers for Disease Control and Prevention (CDC).

This document serves as an addendum to the Interagency Agreement (number 00FED05404) between the Centers for Disease Control and Prevention and the U.S. Consumer Product Safety Commission covering the expansion of the National Electronic Injury Surveillance System (NEISS) to collect data on all injuries. This addendum covers a special study entitled: "The NEISS Special Study of Brain Injury" which is outlined below.

I. DESCRIPTION OF SERVICES

PROPOSED NEISS SPECIAL STUDY OF BRAIN INJURY

Purpose:
This study will examine the suitability of obtaining national estimates of the incidence of traumatic brain injury (TBI) treated in US hospital EDs, using NEISS All-Injury Project (NAP) data, and the suitability of using NAP data for ongoing surveillance of TBI.

The sensitivity and predictive value positive (PVP) of head injuries identified in NEISS have not been fully evaluated using the CDC clinical definition of TBI (or craniocerebral trauma) as a standard. The Consumer Product Safety Commission, in collaboration with CDC, will conduct a NEISS Special Study of Brain Injury to assess the best approach to identifying and characterizing ED cases with TBI and to assess the potential of NAP data to distinguish actual TBI from other (extracranial) head injuries. This would include a determination of the availability of pertinent information commonly used to define brain injury and an evaluation of PVP and sensitivity. From this Special Study, we expect to gain insights in order to make recommendations for better identifying and characterizing TBI using NEISS.

Methods:

1. Preliminary Pilot Study.

    a. Description: a small pilot study will be conducted to assess the suitability of special screen questions used in the Principal Study (see below).
    b. Sample: 50 cases total—we recommend 10 cases drawn from 5 NEISS hospitals (representing different hospital strata—small, medium, large, very large, children's) to test the special screen questions given below.

c. Case definition: any NEISS All-Injury Program case (any injury, any age) where an injury to the brain, head, face, skull, scalp, eye, or ear is noted or alluded to ANYWHERE on the ED record (it need not be the primary diagnosis). For the Preliminary Pilot Study only, in half the sample (n = 25), cases should not be coded as having concussion or internal organ injury; in the other half of the sample (n = 25) cases should be coded as having concussion or internal organ injury.

d. Data collection: ED records will be reviewed and data abstracted to answer special screen questions described in Item II.D., below. The data will be recorded on a paper questionnaire and sent to CDC. We request that the emergency department (ED) records of these selected cases be photocopied and held by CPSC for the duration of the pre-pilot study, in order that these can be reviewed if unanticipated questions arise.

e. Schedule: This Preliminary Pilot Study will be initiated during the last quarter of FY2000.

f. Analysis of Preliminary Pilot Study data will be done by CDC and results shared fully with CPSC.

2. Principal Special Study

a. Hospital Sample: A nationally representative subsample of NEISS All-Injury Program hospitals, including small, medium, large, very large, and children's hospitals, and representing patients of all ages.

b. Number of NEISS ED Records to be abstracted: A total of 1000 cases are requested (in addition to the 50 reviewed in the Preliminary Pilot Study).

c. Case definition: Any NEISS All-Injury Program case (any injury, any age) where an injury to the brain, head, face, skull, scalp, eye, or ear is noted or alluded to ANYWHERE on the ED record (it need not be the primary diagnosis).

d. Data Collection: For each subject who meets the case definition, the following questions should be answered on a special screen (a supplementary computerized '2nd screen'), based on information provided in the ED record. These questions may be modified based on findings of the Preliminary Pilot Study (see Section I, above).

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Did the patient lose consciousness at any time? (E.g., was "LOC" noted)?	Y	N	DK
Did the patient experience amnesia? (E.g., Did the patient experience a short-term memory loss or inability to recall the injury event?)	Y	N	DK
Did the patient have any alteration of consciousness? (E.g., Was the patient described as confused, disoriented, dazed, obtunded, stuporous, comatose, unconscious, difficult to arouse, or unarousable?)	Y	N	DK
Record the total Glasgow Coma Score (GCS), if noted.	_____ (range 3 - 15)		DK
Was the patient under the influence, or possible influence, of alcohol or illicit drugs at the time of the injury?	Y	N	DK
Was a head CT scan done?	Y	N	DK
Record verbatim results of the CT scan below: [est. 160 characters needed] _____ _____			
Record narrative description of head injury if not listed as principle diagnosis in NEISS DIAGNOSIS field. [est. 100 characters needed] _____ _____			
Coder comments: What problems, if any, were encountered in answering these questions or coding this case? [est. 160 characters needed] _____ _____			

e. The Special Study data obtained for these sampled cases should be matched and merged with standard NEISS All-Injury Program data obtained from these cases. These standard NAP data elements should include (but not be limited to) matchable unique case identifiers, age, sex, race, ethnicity, treatment date, work-relatedness, injury mechanism and intent, body-part injured, diagnostic information, and disposition (admitted vs. not admitted to hospital). CDC can match data sets.

f. At the end of the study we propose administering a brief questionnaire to coders to elicit recommendations for improving the coding of data and the

discrimination of TBI from other types of head injury. This questionnaire will be developed during the pilot study.

g. Schedule: The Principal Special Study will commence following the analysis of Preliminary Pilot Study data. We anticipate that the Principal Special Study will commence early in the second quarter of FY 2001, that data will be collected in an interval of approximately 1 month, and that the preliminary analysis of data will be completed in the third quarter of FY 2001.

h. Analysis of data will be done by CDC and methods and results shared with CPSC.

II DURATION OF AGREEMENT

This agreement is approved from the date of signature for both agencies through June 30, 2001.

III ESTIMATED COSTS

Estimates costs are $50,000.00. This cost estimate is broken down into the following sub-categories:

- Data base programming (Estimated cost = $10,000)
  An additional '2nd screen' will be added to the NEISS data entry programs used by the NEISS hospital coder to collect the information discussed in section I.2.d. All appropriate data bases and programs will be modified to accommodate the collection of this additional data.

- EPDS oversight (Estimated cost = $25,000)
  Hospitals will be paid on a per case basis for the 50 preliminary and 1,000 principle cases at a negotiated supplemental rate for the '2nd screen' information. Data Systems (EPDS) staff will write a study objectives section to be added to the hospital coding manual, recruit a subset of NEISS hospitals to participate in this study, and train the participating hospitals. EPDS staff will also track the collection of data, perform routine quality control on the data, extract the data for CDC review, and administer any follow-up questionnaires to the participating NEISS hospitals.

- CPSC General and Administrative Costs (Estimated cost = $15,000)

IV FUNDING

All funds provided by CDC in this agreement must be obligated by the performing agency by the end of the fiscal year in which the funds expire. Any unobligated but expired funds may not be used to fund services in subsequent periods. The CDC

Financial Management Office (FMO) must be notified of any unobligated funds pertaining to this agreement at least 15 days before the end of the fiscal year so that the agreement can be amended to reduce the obligated amount when appropriate. The notification must be provided to the address cited below (in paragraph V).

5. ACCOUNTING AND BILLING INFORMATION

Funds for this project for FY2000 in the amount not to exceed $50,000.00 will be transferred to CPSC via OPAC using the following account data:

	From	To
Agency	CDC	CPSC
Agency Symbol	75-09-0421	4610000010
Appropriation	7590943	00 EXOB-PS 4310.00
CAN	09212307	0011179 25.2105
Object Class	25.39	
Amount	$50,000	$ 50,000
EIN No	58-6051157	52-0978750

When billing CDC through the OPAC system, CPSC will reference agreement number 00FED05404-01.

When funds are provided to the performing agency in advance of services being performed or goods being delivered, the performing agency is required to provide, within 15 days of the end of each quarter, statements of obligations and expenditures made during the quarter. These statements are also provide to the address below:

CDC, FMO
Attn: OPAC Desk
1600 Clifton Road, MS D-06
Atlanta, GA 30333

6. EQUIPMENT

There is no equipment to be covered under this agreement.

7. TRAVEL

No travel costs are associated with this Interagency Agreement.

8. CONFLICT WITH EXISTING AGREEMENTS

There is no duplication or conflict with existing agreements, policy, or statute.

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9. PROGRAM CONTACTS

CDC: David J. Thurman M.D.
NCIPC, DACRRDP (F41)
4770 Buford Highway, NE
Atlanta, Georgia 30341-3714
(770) 488-4715

CPSC: Art McDonald
CPSC
4330 East West Highway. Rm 604D
Bethesda, MD 20814-4408
(301) 504-0539 x1246

10. BUDGET CONTACTS

CDC: Deborah Mathis
NCIPC/OD (K62)
4770 Buford Highway, NE
Atlanta, Georgia 30341-3724
(770) 488-4695

CPSC: Robert J. Frost
Contracting Officer, CPSC
4330 East West Highway, Rm 517
Bethesda, MD 20814-4408
(301) 504-0444

XI. MODIFICATION AND CANCELLATION

This agreement may be modified by mutual consent of both parties or canceled upon 60 days advance written notice by either party.

XII. AUTHORITY

This agreement is entered into under Section 601 of the Economy Act, as amended (31 U.S.C. 1535) and the Consumer Product Safety Act.

XIII. APPROVALS

For NCIPC:

for Deborah A Mathis

Stephen B. Thacker, M.D., M.Sc.
Assistant Surgeon General
Acting Director, National Center for Injury Prevention and Control

Date: 8/21/00

For CPSC:

for Thomas W Murray

Pamela Gilbert
Executive Director
U.S. Consumer Product Safety Commission

Date: 9/1/00